EXHIBIT 159

BLEND FAILURE INVESTIGATION

OVERVIEW:

[redacted]

An increase of blend analysis failures has been noted since the changeover to slugs. An investigation was initiated to determine the root cause and to implement the necessary corrective action and preventive action (CAPA) which we believe was due to handling and storage of the samples.

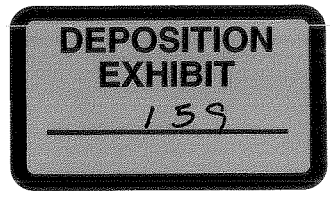
Thief sampling methods, handling of samples including the storing of samples in plastic bags and glass scintillation bottles were investigated. New thiefs with sampling compartments based on the volume (run weight) of product to be sampled have been ordered. By changing the sampling procedure and using glass scintillation bottles, we believe that the problem has been resolved.

A table of all initial blend failures is found on the next page.

Situation Analysis:

Prior to January 9, 2007, samples were taken from the blender using a thief containing sampling compartments. A large sample size was taken and a one dose weight was withdrawn for analysis.

[redacted]



[redacted]

Digoxin Tablets 0.125mg Batches 70148A and 70207A failed slugging blend analysis. Batch history showed no blend issues and the batches were compressed and tested. 30 additional tablets were tested and results were within specifications. These batches were released.

Table of Powder/Slugged Batches OOS

OOS #	Batch #	Product	Powder/Slug	Disposition
[redacted]				
OOSNO7-016	70148A	Digoxin Tab, 0.125mg	Slug	Released with additional testing
[redacted]				
022	70207A	Digoxin Tab, 0.125mg	Slug	Released with additional testing
[redacted]				

Blend sampling using the slug method was witnessed. The sampling by a thief was performed by the same Q.A. sampler.

Some issues were noted.

Dropping of powder into the slug device.

Powder was lost.

Thief and slug device are not cleaned between samples

Use of plastic bags

Powder adhering to the sample compartments

Powder falling between the wall of the thief and the sampling compartment.

Blend sampling to be submitted as powder was also witnessed. Some issues noted include:

All of the above

To obtain the sample weight, the powder is transferred to another weigh paper on a balance in the QA office. The sample is transferred to another weighing paper envelope and placed in a plastic bag. The laboratory withdraws only a portion of one dosage unit for analysis.

Globepharma Inc, a distributor of Quality Pharmaceutical Equipment was called to assist Actavis address our sampling problem. The discussion centered on developing a blend sampling procedure to eliminate /reduce the rate of blend failures seen the last few months.

The discussion centered on the following:

Sampling Thief Storage and Cleaning

1. Log books for thief usage and cleaning
2. Storage of thief in plastic bags
3 Globepharma would provide a source with phone #.
4. Identification numbers for each thief
5. SOP for thief usage
6. Cleaning of thief

Purchasing of Dyes

1. Dye sizes
2. Multiple dyes
3. Calculation of volume required for the various dye sizes using bulk density
4 Tabulation of thiefs with dye sizes, run weight, bulk density, etc
5. Sample size required (2x or 3x, etc for each dosage)

Sampler

1. Metal tube with delron lined inner tube to prevent metal contamination
2. When closing the thief to pull duplicate samples, the chamber is to remain upright and the housing rotated.
3. Thief size depending on the blender size
   1 unit dose - 1.5 inch distance from end of sampler
   2 unit dose – 3.5 inches from end of sampler
   3 unit dose – 5.5 inches from end of sampler

Delivery of Blend Samples to QC

1. Pre washed amber glass vials with cap having Teflon liner or pre washed amber glass bottle with cap having Teflon liner
2. Bottle size and mouth diameter
3. Labeling of vials or bottles

Globepharma Recommendations

1. High dose products should be sampled as powder (50 mg or > active)
2. Low dose products should be slugged (< 50 mg)
3. Combination of low and high dose product should be slugged

Based on the discussion, we modified our sampling approach.

1. Sampling protocols will be written for each confirmed failure. The protocols will include 3 different types of sampling using the thief and sampling compartments.
2. Samples will be taken and placed in pre-weighed glass vials. The vial contents will be transferred to the volumetric flasks and the vial rinsed and weighed to obtain the sample weight.
3. Slugged samples will be placed in glass vials and weighed prior to analysis
4. Samples will be placed in weighing paper and transferred to the lab.

Samples were tested by the R&D laboratory. The data reported for [redacted] confirmed the acceptance criteria for glass vials with limited sample handling. However samples in the weighing paper having additional handling failed specifications.

Based on the R&D data, we have decided to write protocols for all blend failures. Based on the dosage weight of the finished product and the bulk density, the target sample volume will be calculated for the dosage weight to be taken. Triplicate samples will be taken from 10 separate locations from the drums in the warehouse. All samples will remain as powder and placed in pre-weighed scintillation glass vials. Sample weights will be recorded. The entire quantity of the vials will be analyzed and the vials rinsed to assure complete transfer of all the powder. If the result of the testing confirms that sampling is the cause, the blend will be considered for release and further processing through normal procedures.

The following additional points listed were investigated:

Low humidity /high sampling

API particle size

Batch Records

Method issues (blend, finished product and stability)

Product validation

Laboratory testing (instrumentation, dissolving, mixing, dilution, human errors, etc.)

% relative humidity recordings for the last 12 months in the two granulation/blending departments were reviewed. Lower values were seen for the months October through April. Dryer conditions may lead to electrostatic attractions which may be the cause for the higher number of blend failures. The samples are placed in a polyethylene bag where again static charges may cause blend failures. Upon transferring the sample some residual powder may be left.

API particle size analysis, bulk/tap density data performed at Actavis were compared to the manufacturer's data when available for lots of API purchased before and sometimes after the lot was used in the failing blend of tablets. Some minor differences were seen but all data was within specifications.

No issues were noted with batch records product validation and laboratory testing.

A meeting was held with the QC laboratory to discuss method issues for all failing blends identified in this report as being slugged. The meeting was extended to include the testing of finished product and stability. No issues were raised. The laboratory meeting discussed also addressed instrumentation, dissolving, mixing, dilution, human errors, etc.) No issues were raised.

A copy of the meeting agenda along with the attendee's signature is attached.

A review of the Annual Product Reviews (APR) for 2004 through mid 2006 wherever available showed only one additional process validation was performed for on one batch [redacted]

CONCLUSIONS:

Sampling, handling and transferring the samples for weighing and analysis may be the issues. A CAPA program has been written addressing how to sample, transfer and analyze product blends. The CAPA is attached to this investigation.

Digoxin Tablets 0.125mg Batch #s 70148A & 70207A passed the 30 additional content uniformity and were released.

[redacted]

[redacted]

In all cases the data will be carefully reviewed. Input will be obtained from R&D. An addendum will be written as new data is generated using the new sampling thiefs and dyes.

Written By: _____ DATE: _____

Leroy Lundner

Associate Director Quality Compliance

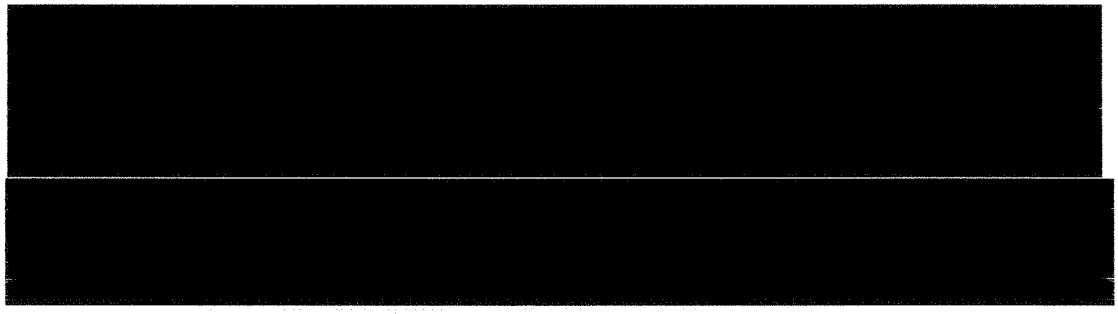
Approved: _____ DATE: _____

Scott Talbot

Site Head Quality

Attachments

1. Corrective Action and Preventive action (CAPA)
2. Table of calculated sampling volumes (Proposed Sampling Technique for Blend Sample)
3. Agenda for blend failure discussion
4. Quality Control training records
5. Quality Assurance in-process personnel training



9. Purchase order for Sampling Thiefs and Dyes